|  |  |
| --- | --- |
| **Radiometer ABL90 Operating and Assay Procedure** | |
| **Purpose** | This procedure provides instructions for RADIOMETER ABL90 OPERATING and ASSAY PROCEDURE. Standard operating instructions necessary for the basic operation of the ABL90 FLEX analyzer are explained in this document. This document includes explanation of the screen elements and operation of ABL90 FLEX Analyzer Status and Sample Measurement. Standard operating instructions contain pre-analytical and analytical phases of the sample measurement as well as basic troubleshooting procedures to ensure the instrument provides continuous quality analytical results.  This procedure also provides instruction on testing and reporting pH, Sodium, Potassium, Chloride, Ionized Calcium, pCO2, pO2, Biocarbonate (calculated), Oxygen Saturation (calculated), Base Excess (calculated), Carboxyhemoglobin, Methemoglobin, Glucose, Lactate, Hemoglobin and Hematocrit by ABL90. |
| **Policy Statements** | * The procedure applies to chemistry staff responsible for the daily operation and verification of the Radiometer ABL90 FLEX Blood Gas Analyzer. * The ABL90 Operating Guide is maintained on-line in G:\Lab\Chemistry\ABL90\ABL90 SOP as the primary procedure manual * Staff trained to operate the ABL90 have secure login using their employee badge * One level of internal quality control (QC) is done once each 8 hour shift. An instrument lock-out is in place for any parameters that do not pass QC. * Required Instrument maintenance will be performed each day of patient testing * Manufacturer’s recommended guidelines are followed. |
| **Principle** | **pH, Na+, K+, Cl-, Ca+**  The pH and electrolyte sensor are of solid-state design with an H+, K+, Na+ and Ca+ sensitive PVC membrane. The Cl- sensor is of slid-state design with a Cl- sensitive epoxy membrane. The pH and electrolyte sensor are measured according to the potentiometric measurement principle, where the potential of an electrode chain recorded at the Voltmeter is related to the concentration of a substance via the Nernst equation.  **pCO2**  The potential differences at all the junctions in the electrode chain are known and constant, except that at the pH-sensitive membrane. The potential difference at the pH-sensitive membrane depends on the pH of the electrolyte solution, which in turn depends on the CO2 content of the sample.  **pO2**  The optical system for pO2 is based on the ability of O2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample.  **Glucose and Lactate**  The Glucose and Lactate sensors are three-electrode sensors which consist of an internal silver/silver chloride reference electrode, a platinum auxiliary electrode and a platinum anode. The sensors are covered by a multi-layer bound to the sensor board. Glucose and Lactate sensors are measured according to the amperometric measurement principle, in which the magnitude of on electrical that is oxidized or reduced at an electrode in the chain. |
| **Analyzer** | Radiometer ABL90 |
| **Sunquest Test Codes** | |  |  |  |  |  | | --- | --- | --- | --- | --- | | PCO2 | PCO2 Arterial blood |  | NA | sodium serum/plasma/whole blood | | VCO2 | PCO2 Venous blood |  | NAP | Sodium pump blood | | CPCO2 | PCO2 Capillary blood |  | K | Potassium serum/plasma/whole blood | | PH | PH Arterial blood |  | KP | potassium pump blood | | VPH | PH Venous blood |  | CL | CHLORIDE | | CBGPH | PH Capillary blood |  | GLUC | GLUCOSE | | PO2 | PO2 Arterial blood |  | LYTE | Electrolyte | | VPO2 | PO2 venous blood |  | HGBB | Hemoglobin | | ICA | IONIZED CALCIUM |  | HCTB | Hematocrit | | PICA | PUMP IONIZED CALCIUM |  | COHB | Carboxyhemoglobin | | LACT | LACTATE WHOLE BLOOD |  | MHGB | Methemoglobin | | LACTP | LACTATE WHOLE BLOOD PUMP |  |  |  | |
| **Materials** | |  |  |  | | --- | --- | --- | | **Equipment** | **Reagents** | **Supplies** | | * ABL90 FLEX Blood Gas System 090R0925N0012   "ABL 12"   * ABL90 FLEX Blood Gas System 090R0925N0013   "ABL 13"   * ABL90 FLEX Blood Gas System 090R0925N0014   "ABL 14"   * ABL90 FLEX Blood Gas System 090R0925N0016   "ABL 16" | * Solution Pack SP90– expires after 600 activities or 30 days * Sensor Cassette SC90- expires 30 day * Inlet Gasket Holder * Inlet connector gasket | * Capillary Clot Catcher   CHC#31841   * Syringe Clot Catcher   CHC#31846   * 70uL capillary tubes   CHC#31840   * Heparinized syringes | |
| **Sample Requirements (cont.)** | **ICA, CL, GLUC, PCO2, PH, PO2, K, NA, TCO2, MHGB, COHB, HGB, HCT, BE, HCO3**:   * Free flowing whole blood sample collected in a heparinized blood gas syringe, and maintained anaerobically. * Free flowing whole blood samples collected in 2 70uL heparinized capillary sample tubes with fleas, and maintained anaerobically. These capillary tubes must be full: 65uL of sample is the absolute minimum volume required.   **Lactate**:   * Free flowing whole blood sample collected in a heparinized blood gas syringe, and maintained anaerobically. **Arterial strongly preferred**. Venous samples are acceptable as long as a tourniquet is not used and hand-clenching is avoided. The sample should be delivered on wet ice. (Append comment –ICE for Lactates not received on ice) * Secondary Specimen Type (not preferred): free flowing whole blood sample collected in 2 heparinized capillary sample tubes with fleas, and maintained anaerobically on wet ice. Capillary samples are strongly discouraged due innate collection trauma. |
| **Sample Requirements (cont.)** | **Serum/ Plasma**: Cl, GLUC, K, NA  **Minimum Volume:** 65uL, or 1 full 70uL capillary tube. Minimum volume will not allow for repeat or testing.  **Stability:** Room Temperature: 30 minutes  Lactate on Wet Ice: 15 minutes  ICA: Room temperature: 2 hours, 4°C for 48 hours  **Rejection Criteria:** Unlabelled specimens, clotted specimens  **Preparation:**   * Mix syringe samples well in two directions: rotating syringe between fingers, taking care not to change the temp of the sample by heat of the hands, and also gently inverting the sample several times. Capillary samples should be mixed 20 times, slowly, along the full length of the capillary tube with a magnet before testing. * NOTE: Specimens on 0-6 month-old neonates should be mixed by **gravity** 10-20 times by gently holding one end up, letting the flea fall to the bottom, and gently inverting.  Mixing with the magnet can cause red cells to burst due to red cell fragility of neonates. Specimen must be completely mixed prior to sampling. * **A clot catcher must be used with every sample**. Use the correct clot catcher for syringe and capillary samples. The clot catcher for syringes should be half full. There is no need to completely fill the clot catcher with sample, as only 65 uL of sample is aspirated. * Test within 10 minutes preferred. DO NOT EXCEED STABILITY TIME. Turn-around time is 15 minutes or less. |
| **Risk & Safety** | Safety data sheets (MSDS/SDS) available on Children’s StarNet. Dispose of used QC ampoules, solution packs, sensor cassettes, and used patient samples as infectious waste. |
| **Calibration** | Due to significant drift, the Glu, Lac, Oxi, and pCO2 calibrations have a reduced validity time for the first 24 hours after cold starts and sensor cassette replacements. The first 24 hours, the validity time of the Glu, Lac, Oxi, and pCO2 calibrations gradually increases to 4 hours (the span between scheduled calibrations). During the first 4 hours, no additional calibrations are scheduled, but a measurement takes up to 3 minutes because a calibration is performed with every measurement. After 4 hours, calibrations are run in fixed intervals according to the table below and a measurement takes 35 seconds.  Time installed Time between calibrations  0-4 hours 0 minutes (performed with every measurement)  4-6 hours 15 minutes  6-8 hours 30 minutes  8-12 hours 60 minutes  12–24 hours 240 minutes  If the analyzer is only turned off for a short period of time and certain preconditions are fulfilled, a warm start may be performed instead of a cold start. For further information about the warm start and the preconditions, see section Warm Start in chapter 10: Analyzer shutdown. When taking ABL90s to surgery for intraoperative testing, the installed batteries should keep the analyzer running to prevent need for shutting down the analyzer. Plug the instrument in immediately upon delivery to selected location. |
| **Analytical Measuring Range (AMR)**  **AMR (cont.)** | * Once every 6 months perform calibration verification and analytical measuring range verification with Radiometer VK kit calibration material. * Record and transmit results by email or facsimile to wdc.radiometeramerica.com * Values must fall into acceptable ranges, and are used to verify reportable range of analytes   Follow procedure [CH 5.06 Calibration Verification and AMR on ABL 90](http://starnet.childrenshc.org/References/labsop/chem/procedure/ch-5.06-calibration-verification-on-abl.pdf) |
| **Quality Control** | 1. Internal QC will run once per shift at the scheduled time. 2. Internal QC will NOT run at the designated time when errors are present.    1. Correct errors    2. Manually schedule Internal QC using Analyzer Status->Quality Control->Highlight correct level->Start QC   Additional quality controls should be run after any troubleshooting or preventive maintenance or whenever a service technician has doubts about the performance of the analyzer |
| **Sampling Procedure**  **Sampling Procedure (cont.)** | |  |  |  | | --- | --- | --- | | **Step** | **Action** | **Related Document** | | 1 | Touch screen to “wake up.” |  | | 2 | Scan employee badge |  | | 3 | Check analyzer status |  | | 4 | Correct all sub-system “yellow lights” if present   1. Press the Yellow Stoplight, Help for help in the current screen, OR 2. Refer to [ABL90 FLEX Operator’s Manual](file:///G:\LAB\Chemistry\ABL%2090\ABL90%20Operator's%20Manual.pdf) |  | | 5 | Gently and thoroughly mix patient sample (by gravity if neonatal specimen), then attach clot catcher appropriate for syringe or capillary tube (remove both capillary caps). **Clot catchers must be used with every sample.** |  | | 6 | **Syringe samples**: Lift the inlet to the syringe position. The default test button is “Syringe 65uL.” Place the tip of the Clot Catcher firmly against the inlet gasket and press it upwards while still holding on to the syringe.  **Capillary samples**: Lift the inlet to the capillary position. The default test choice is “Capillary.” Press the capillary tube against the inlet gasket. Gently press the inlet gasket slightly to make a complete seal between the capillary clot catcher and the inlet gasket. |  | | 8 | Remove sample when prompted by tone and screen and close the inlet. |  | | 9 | For every patient sample, utilize Dynamic Ordering in compliance with Children’s Risk Management mandate: Deselect by pressing the square(s) so that there is no green check for any tests that are not ordered. A check mark in the box means the test will be reported. (Unselected tests can be added on at a later time if ordered by the provider, even if the test is not initially selected. See Add On section below.) |  | | 10 | Scan the specimen barcode and select sample type. |  | | 11 | Confirm correct patient information has downloaded from the Sunquest accession number. |  | | 12 | If the patient information does not download, print the patient result and attach the Sunquest label. |  | | 13 | Review results before reporting   1. Review results shown on the ABL screen for error messages, critical results, reportable ranges or other inconsistent values. 2. Refer to result reporting to release results in Sunquest. |  | | 14 | Log off analyzer when finished. |  | |
| **Add-On Testing** | |  |  | | --- | --- | | 1 | Press Data Log (top right on ABL90 screen) | | 2 | Select Patient Result Log | | 3 | Highlight the appropriate specimen | | 4 | Press Result (lower left corner). Patient specimen results will open. | | 5 | If using the same accession number, proceed to step 6. If the added tests are on a different accession number, Press ID (lower left corner). Change the sample ID to match the new accession number. If the letter of the accession number is removed, the keyboard must be used to replace the letters and numbers. Ensure the letter in the accession number is capitalized. Then touch the Back button. | | 6 | Select the Parameters button. Select which test(s) were added on. (a black check mark will appear) | | 7 | Press Back | | 8 | The added-on results will show up on the result screen | | 9 | Press Send (lower middle) to send the result across the interface to Sunquest for resulting. | |
| **Alternate Method** | If in the unlikely event all 4 ABL90 analyzers are out of service, blood gas samples should be tested by qualified iSTAT operators at point of care. |
| **Replacing Sensor Cassette** | |  |  |  | | --- | --- | --- | | Step | Task | Action | | 1 | Press Menu > Analyzer status > Replacements > Replace >  Replace sensors  ***FOLLOW ON-SCREEN PROMPTS/VIDEO INSTRUCTIONS*** | See [Operator’s Manual, Section 7 Replacements](file:///G:\LAB\Chemistry\ABL%2090\ABL90%20Operator's%20Manual.pdf) | | 2 | Remove the old sensor cassette by pulling it upwards and out of the compartment with thumb and index finger. Dispose of the used sensor cassette as infectious waste according to the regulations in your institution |  | | 3 | Peel off the silver label, unscrew the blue top, and remove the new sensor cassette. |  | | 4 | Press the new sensor cassette firmly into the sensor cassette seat in the sensor compartment until resistance is met. You will not hear a click. |  | | 5 | Press ***Proceed***. The sensor cassette compartment closes and a new **Replacing sensor cassette** screen appears |  | | 6 | Enter operator ID and any notes. For example, if there was an error on the previous sensor cassette, make a note here. Confirm the entry with the ***Enter*** button |  | | 7 | Press ***OK*** to finish or press ***Replace solutions*** to also replace the solution pack – see *Replacing* *Solution Pack* below |  | | 8 | Wait until the restart sequence has been finished | The calibration and Internal QC status are checked 1, 2 and 3 hours after sensor startup. | |
| **Replacing Solution Pack** | |  |  |  | | --- | --- | --- | | Step | Task | Action | | 1 | Press ***Menu > Analyzer status > Replacements > Replace > Replace solutions. FOLLOW ON-SCREEN PROMPTS/VIDEO INSTRUCTIONS*** | See [Operator’s Manual, Section 7 Replacements](file:///G:\LAB\Chemistry\ABL%2090\ABL90%20Operator's%20Manual.pdf) | | 2 | Lift the inlet to the capillary position and wait for the solution pack to unlock. |  | | 3 | Remove the used solution pack and dispose of in biohazard bin |  | | 4 | Activate the new solution pack by  pulling out the red plastic safety pin |  | | 5 | Press the lid VERY FIRMLY down by pressing the elevated side (where the safety pin was) down **until the side tabs click into the side tab holes.** This allows the solution packs to be punctured so that solutions will flow through the analyzer. |  | | 6 | Remove the top layer of the label on top of the solution pack, so that the biohazard label appears to remind you that the solution pack must be disposed of as infectious waste after use. |  | | 7 | Insert the new solution pack by pushing it fully into place while holding onto the sides of the analyzer until a click is heard. Maintain pressure on the solution pack until the screen changes. |  | | 8 | When prompted by the analyzer, close the inlet.  Enter operator name and any notes, using the ***Keyboard*** or the ***Note*** button to display the keyboard. Confirm the entry with the ***Enter*** button on the keyboard. |  | |
| **Reference Ranges** | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Reference Range** | **pH** | **pCO2** | **pO2** | **O2S** | | Arterial | 7.35-7.45 | Male: 35-48 mmHg  Female: 32-45 mmHg | 80-105 mmHg | 95-99 | | Venous | 7.31-7.41 | 40-52 mmHg | 30-50 mmHg | N/A | | Capillary | 7.35-7.45 | Male: 35-48 mmHg Female: 32-45 mmHg | N/A | N/A | | **AMR** | 6.76-7.84 | 8-112 mmHg | 11-625 mmHg | 4-100 | | **CRITICAL VALUE** | <7.20 or >7.60 | <15 or >70 mmHg | Arterial: <40 mmHg | None defined |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | **Na mEq/L** | **Cl mEq/L** | **LACT mg/dL** | **COHB %** | **MetHB** | | **Reference Range** | 137-147 | 98-106 | 4.5-19.8 | 0.1.5 | 0.4-1.5 | | **AMR** | 77-178 | 44-125 | 1-270 | 0.4-50 | 0.1-30 | | **Critical Value** | <124 or >156 | None defined | >45 | None defined | None defined |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Ionized Calcium mEq/L** | | **Glucose mg/dL** | | **K mEq/L or mmol/L** | | | **Reference**  **Range** |  | **Reference Range** |  | **Reference Range** |  | | 0-7 days | 2.10-2.96 | 0-30 days | 60-90 | 0 days- 1 year | 3.3-5.9 | | > 18 years | 2.32-2.64 | >12 years | 70-100 | >12 years | 3.5-5.3 | | **AMR** | 0.3-3.9 | **AMR** | 1-1200 | **AMR** | 0.8-14.3 | | **Critical Value** | <1.5 | **Critical Value** | <50 or >300 | **Critical Value** | <2.5 or >6.5 |  |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **HGB mg/dL** | | **Hct %** | | | **Reference range** | Male | Female | Male | Female | | 0-7D | 14.5-22.5 | 14.5-22.5 | 45-67 | 45-68 | | 7-14 D | 13.5-19.5 | 13.5-19.5 | 42-66 | 42-67 | | 15 D- 1M | 12.5-20.5 | 12.5-20.5 | 39-63 | 39-64 | | 1M-2M | 10.0-18.0 | 10.0-18.0 | 31-55 | 31-56 | | 2M-3M | 9.0-14.0 | 9.0-14.0 | 28-42 | 28-43 | | 3M-6M | 9.5-13.5 | 9.5-13.5 | 29-41 | 29-42 | | 6M-2Y | 10.5-13.5 | 10.5-13.5 | 33-49 | 33-50 | | 2Y-6Y | 11.5-15.5 | 11.5-15.5 | 34-40 | 34-41 | | 6Y-12Y | 11.5-15.5 | 11.5-15.5 | 35-45 | 35-46 | | 12Y-18Y | 13.0-16.0 | 12.0-16.0 | 13.0-16.0 | 33-51 | | >18Y | 13.5-17.5 | 12.0-16.0 | 37-53 | 33-51 | | **AMR** | 4 - 23 | |  | | | **CRITICAL VALUE** | <7gm/dL | <7gm/dL | <21 o >65 % | <21 o >65 % | | HemOnc: <5 gm/dL | HemOnc: <5 gm/dL | HemOnc: None | HemOnc: None | |
|  |
| **Limitations** | ***A negative Anion Gap strongly suggests laboratory instrument error*.** Repeat electrolyte tests using an alternate system. Evaluate test systems and Quality Control procedures. Report confirmed results. |
| **As-Needed Maintenance** | |  |  |  | | --- | --- | --- | | **Step** | **Task** | **Action** | | 1 | Cleaning inlet gasket holder | [Video](file:///G:\LAB\Chemistry\ABL%2090\USB%20Drive%20from%20Radiometer%20Information\ABL90%20Children's%20Hospital%20-%20Minneapolis\04%20Inlet%20gasket%20cleaning%20and%20replacement.wmv) | | 2 | Clean touch screen and exterior | Use DI water (sparingly) and a lint-free tissue. Dry using a separate lint-free tissue. | |
| **Monthly Maintenance** | |  |  |  | | --- | --- | --- | | **Step** | **Task** | **Action** | | 1 | Perform Instrument Correlations.  **Do not use EDTA** as it will decrease the lifetime of the sensor. | Refer to [CH 2.05 Instrument Correlation procedure](http://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.05-instrument-correlation.pdf) | |
| **Quarterly Maintenance** | |  |  |  | | --- | --- | --- | | Step | Task | Action | | 1 | -Replace Inlet Gasket holder  -Replace Inlet connector gasket | [Replace Inlet Gasket Holder Video](file:///G:\LAB\Chemistry\ABL%2090\USB%20Drive%20from%20Radiometer%20Information\ABL90%20Children's%20Hospital%20-%20Minneapolis\04%20Inlet%20gasket%20cleaning%20and%20replacement.wmv)  [Replace Inlet Connector Gasket Video](file:///G:\LAB\Chemistry\ABL%2090\USB%20Drive%20from%20Radiometer%20Information\ABL90%20Children's%20Hospital%20-%20Minneapolis\02%20Connector%20gasket%20mounting.wmv) | |
| **Analyzer shutdown/ Restart** | Refer to the Operating Manual Chapter 10. Depending on the type of shutdown, there is a corresponding Restart to follow in chapter 10. |
| **Battery Level Indicator** | The analyzer is connected to main power. Battery is charging and power level is indicated by %.  The analyzer is running on battery. Battery charge level is indicated by a percentage.      If the battery level is less than 25%, the battery charge level in the icon is yellow. A system  message is shown in the Activity log. Corrective action: Connect the analyzer to main power.  If the battery level is less than 13% the battery charge level in the icon is red. A message  is shown on the screen. Corrective actions: Connect the analyzer to main power, close the  dialogue box.  At 10%, the analyzer shuts down. Corrective actions: Connect the analyzer to main power, turn on the analyzer. |
| **Troubleshooting** | Refer to [Operators Manual Section 11. Troubleshooting](file:///G:\LAB\Chemistry\ABL%2090\ABL90%20Operator's%20Manual.pdf) for user-available troubleshooting procedures. If unable to successfully resolve problems, call Radiometer Technical Support. |
| **Training Plan/**  **Competency Assessment** | Use [ABL90 Initial Training Checklist](file:///G:\LAB\Chemistry\ABL%2090\USB%20Drive%20from%20Radiometer%20Information\ABL90%20Children's%20Hospital%20-%20Minneapolis\Customer%20Materials%20from%20CD\5_ABL90_TrainChecklist.pdf) for initial employee training. StaffReady software program will be used to perform annual Competency Assessments after initial training on the ABL90. |
| **Result Reporting** | See table above for AMR   * If result is less than the AMR, result the patients as < the AMR value instead of numerical value * If results if greater than the AMR, result the patients as > the AMR value instead of numerical value * Results from samples suspected of IV solution contamination should have a comment appended to the result.   -QR = questionable result, ?Line contamination  -CONA = contamination of line draw?/ redrawn |
| **Sample Storage** | Following testing, place samples in biohazard containers. Dispose of containers when ¾ full |
| **References** | * ABL90 Operator’s Manual from software version 3.1xx, 201403A, 996-281 |
| **Historical Record** | |  |  |  |  | | --- | --- | --- | --- | | **Version** | **Written/Reviewed By** | **Effective Date** | **Summary of Revisions** | | 1 | Stephen Gripentrog, Erin Bartos | 6/12/2018 | New Procedure | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |